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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,375	06/02/2005	Giuseppe Sasso	02508.0107	7553

22852 7590 11/14/2006

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EXAMINER

SOROUS, ALI

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 11/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/500,375

Applicant(s)

SASSO ET AL.

Examiner

Ali Soroush

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 9 rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim.

Claims 4 and 9 recite the term "substantially" rendering the claims indefinite in that it fails to point out the metes and bounds of "matching the partial pressure value of carbon dioxide exhibited by said bicarbonate solution". The term "substantially" makes unclear how similar the partials pressure values of carbon dioxide between the acid solution and the bicarbonate solution is necessary.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Veech (US 5200200, published 04/06/1993).

Veech teaches, "The invention lies in the field of methods for the perpetration of therapeutic aqueous solutions which contain dissolved therein at the time of use unstable metabolites of the type normally present in human blood plasma, and also to

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the field of filled storable containers useful for the storage of such solutions in unit dose forms." (See column 1, Lines 12-18). "Flexible walled containers incorporating plastics and/or metal foil are currently of growing interest in medical environments and the like. Heretofore, various plastic containers containing integrally a plurality of chambers have been provided for storage of therapeutic materials. Each chamber holds one or a group of separatable components which are admixed into a common solution by chamber wall rupture internally before solution use." (See column 1, Lines 60-67). Veech further teaches, "a method for administration of a redox active parenteral therapeutic solution comprising the steps of (A) dissolving in sterile and substantially pyrogen free water inorganic salts and carbon dioxide which are also both sterile and substantially pyrogen free thereby producing an aqueous solution having the following composition:

Component	Quantity (in mMoles/Liter)
Na^+	130-165
K^+	0-5
Ca^{++}	0-2.5
Mg^{++}	0-1.5
Cl^-	90-120
HCO_3^-	.5-60
CO_2	.1-25

..." (See claim 1). Veech teaches more specifically for a redox active peritoneal dialysis solution comprising:

“

Component	Quantity (in mMoles/Liter)
Na ⁺	130-165
K ⁺	0-5
Ca ⁺⁺	0-2.5
Mg ⁺⁺	0-1.5
Cl ⁻	90-120
HCO ₃ ⁻	.5-60
CO ₂	1.2-2
Glucose	80-250

... wherein solution additionally contains from about 01. to 45 mM/liter of l-lactate ions ”

(see claims 4 and 5). Veech also teaches a sodium bicarbonate composition

comprising: particulate NaHCO₃, Na acetoacetate, and particulate Na pyruvate. (See

column 8, Lines 19-22). The sodium bicarbonate composition is added to water and

charged (placed) into the lower chamber of the container and sealed. The redox active

peritoneal solution is charged into the upper chamber of the container and the chamber

is sealed. (See column 7, Lines 36-44). When the tabs separating the two chambers are

pulled apart the two solutions intermix providing the desired dialysis solution. (See

column 8, Lines 27-31). Veech also teaches that the pH of the peritoneal dialysis

solution is 5. (See column 8, Line 15). In regards to the partial pressure value of carbon

dioxide, the composition of Veech is the same as the composition of the instant

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invention. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Veech (US 5200200, published 04/06/1993) in view of Segers et al. (US 5383324, published 01/24/1995).

Applicant Claims

A multiple compartment flexible bag assembly having in one compartment an aqueous sodium bicarbonate solution and in a second compartment an aqueous acid component, comprising: glucose, acid, sodium, potassium, calcium, magnesium, chloride, and dissolved CO₂. Wherein the multiple component flexible bag is over-wrapped in a flexible gas-impermeable plastic material.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Veech teaches, "The invention lies in the field of methods for the perpetration of therapeutic aqueous solutions which contain dissolved therein at the time of use unstable metabolites of the type normally present in human blood plasma, and also to the field of filled storable containers useful for the storage of such solutions in unit dose forms." (See column 1, Lines 12-18). "Flexible walled containers incorporating plastics and/or metal foil are currently of growing interest in medical environments and the like. Heretofore, various plastic containers containing integrally a plurality of chambers have been provided for storage of therapeutic materials. Each chamber holds one or a group of separable components which are admixed into a common solution by chamber wall rupture internally before solution use." (See column 1, Lines 60-67). Veech further

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teaches, "a method for administration of a redox active parenteral therapeutic solution comprising the steps of (A) dissolving in sterile and substantially pyrogen free water inorganic salts and carbon dioxide which are also both sterile and substantially pyrogen free thereby producing an aqueous solution having the following composition:

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..." (See claim 1). Veech teaches more specifically for a redox active peritoneal dialysis solution comprising:

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CO ₂	1.2-2
Glucose	80-250

... wherein solution additionally contains from about 01. to 45 mM/liter of l-lactate ions”
(see claims 4 and 5). Veech also teaches a sodium bicarbonate composition comprising: particulate NaHCO₃, Na acetoacetate, and particulate Na pyruvate. (See column 8, Lines 19-22). The sodium bicarbonate composition is added to water and charged (placed) into the lower chamber of the container and sealed. The redox active peritoneal solution is charged into the upper chamber of the container and the chamber is sealed. (See column 7, Lines 36-44). When the tabs separating the two chambers are pulled apart the two solutions intermix providing the desired dialysis solution. (See column 8, Lines 27-31). Veech also teaches that the pH of the peritoneal dialysis solution is 5. (See column 8, Line 15). In regards to the partial pressure value of carbon

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dioxide, the composition of Veech is the same as the composition of the instant invention. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present.

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Veech lacks the teaching of the multiple compartment flexible bags being over-wrapped in a flexible gas-impermeable plastic material. This deficiency is cured by the teachings in Segers et al.

Segers et al. teaches, "The present invention relates generally to peritoneal dialysis. More specifically, the present invention relates to manufacturing and storing bicarbonate peritoneal dialysis solutions." (See column 1, Lines 6-9). "The device includes an exterior body. The exterior body can be made of any rigid or flexible material that is permeable to water and carbon dioxide." (See column 5, Lines 9-11). Segers et al. further teaches, "The overpouch or second container surrounds both the device and the bicarbonate container. The overpouch is made of any material with low permeability to gas and specifically, carbon dioxide. The low permeability of the overpouch prevents CO₂ from escaping ..." (See column 6, Lines 18-23 and Figure 2).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in art at the time of the invention to use the overpouch of Segers et al. with the invention of Veech. Both patents teach inventions that are to store solutions having carbon dioxide as a component and to be utilized for dialysis purposes. One would be motivated to use the Segers et al.'s overpouch because the plastic containers used by Veech appear to be formed of materials through which carbon dioxide is diffusible. This loss of carbon dioxide leads to the increase in pH of the bicarbonate solution, which leads to the precipitation of calcium carbonate from the solution. The use of the overpouch made of material of low permeability to carbon dioxide would limit the loss of carbon dioxide.

Conclusion

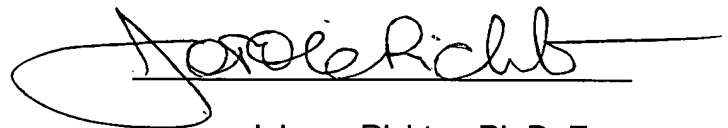
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ali Soroush
Patent Examiner
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A handwritten signature in black ink, appearing to read "Johann Richter", with a large, stylized loop at the beginning and a horizontal line extending to the right.

Johann Richter, Ph.D. Esq.
Supervisory Patent Examiner
Technology Center 1600